

### **THE OFFICE ACTION**

In the Office Action issued on November 17, 2004, the Examiner rejected claims 1-20 under 35 U.S.C. §112, first paragraph, for containing new subject matter. The Examiner also rejected claims 1-20 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter. The Examiner rejected claim 20 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,317,540 to Wakeman ("Wakeman"), DE19712565, WO 91/07876 to Vandeveld et al ("Vandeveld"), and DE4137544 to Harwardt et al. ("Harwardt"). The Examiner further rejected claims 1-6, 9-13 and 17 under 35 U.S.C. §103(a) as being unpatentable over Wakeman. The Examiner also rejected claims 1-20 under 35 U.S.C. §103(a) as being unpatentable over Vandeveld. The Examiner also rejected claims 1-20 under 35 U.S.C. §103(a) as being unpatentable over Harwardt. The Examiner also rejected claims 1-20 under 35 U.S.C. §103(a) as being unpatentable over DE19712565.

### **REMARKS**

Applicants have carefully considered the Office Action issued on November 17, 2004. Applicants respectfully request reconsideration of the application in light of the above amendments and the following comments.

#### **A. Claims 1-20 Comply with 35 U.S.C. §112**

The Examiner rejected claims 1-20 under 35 U.S.C. §112, first paragraph, as containing new subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. Specifically, it is the Examiner's position that the recitation of "tinea pedis" is new subject matter not supported in the original application. Applicants submit that amendments made to claims 1 and 20 now render such a rejection moot. Specifically, the recitation "tinea pedis" has been removed from these claims.

The Examiner also rejected claims 1-20 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter. Specifically, the Examiner stated that the broad recitation of "herpes simplex virus" followed by the specific recitation including the particular herpes conditions renders the claims indefinite. Applicants submit that amendments

made to the appropriate claims removing the particular herpes diseases now render such a rejection moot.

In light of the above, withdrawal of this rejection is respectfully requested.

**B. The Pending Claims Are Not Anticipated by Wakeman, Vandeveldt Harwardt or DE19712565**

The Examiner rejected claim 20 under 35 U.S.C. §102(b) as being anticipated by Wakeman, Vandeveldt, Harwardt and DE19712565. Applicants respectfully traverse.

In support of this rejection, the Examiner states that the above references disclose tosylchloramide preparations that may be suitable for various applications. None of these references, however, disclose compositions containing tosylchloramide or salts thereof effective in treating the recited diseases of the skin. The Examiner states that "it is well settled that 'intended use' of a composition or product...will not further limit claims drawn to a composition or product." This is not an exactly correct statement of the law, however. It is true that the discovery of a new use or property of an old product does not render a composition claim patentable, but only if the old product inherently possesses the claimed property or is capable of performing the intended use. Thus, statements in a preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the intended use results in a structural difference between the claimed invention and the prior art. If so, the recitation serves to limit the claim and patentably define it over the prior art. *In re Otto*, 312 F.2d 937 (CCPA 1963).

Inherency must be a necessary result, not merely a possible result. *In re Oelrich*, 212 USPQ 323 (CCPA 1981); *Ex parte Keith*, 154 USPQ 320 (POBA 1961). See also, *In re Robertson*, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999).

In relying on a theory of inherency, the Examiner must provide a basis in fact or technical reasoning to support the determination that the allegedly inherent characteristics necessarily flow from the teachings of the prior art. *Ex parte Levy*, 17 USPQ2d 1461 (BPAI 1990).

Here, the Examiner has provided no justification that the preparations described in Wakeman, Vandeveldt, Harwardt and DE19712565 would necessarily be suitable for the treatment of the claimed skin diseases. The mere fact that these compositions contain tosylchloramide does not establish inherency of these

compositions to treat such diseases. The Applicants point the Examiner to pages 1-3 of the present application, which discuss these references and how their use in various applications differ from the presently claimed disease treatments. Applicants would like to particularly point out the discussion relating to Vandeveld and how the treatment of retro-viruses as described therein is completely different from the treatment of the present skin diseases. Just because the composition of Vandeveld is suitable for use against retro-viruses provides not support for an assertion that it is suitable for treatment of the claimed skin diseases.

Thus, Applicants submit that the recited intended use patentably distinguishes the claimed compositions over the cited references and request withdrawal of this rejection.

**C. The Present Claims Are Not Obvious Over Wakeman, Vandeveld Harwardt or DE19712565**

Wakeman is directed to the use of quaternary ammonium aromatic sulfonamides for disinfection and as bacteriostat agents (col. 3, line 13 – col. 4, line 15). Wakeman neither discloses nor suggests a method for the treatment of the specifically claimed diseases by administering compositions containing tosylchloramide(s), tosylchloramide salt(s), and mixtures thereof. In support of his rejection, the Examiner states that it would have been obvious to use the compositions of Wakeman in the treatment of the presently claimed skin diseases because Wakeman discloses the use of tosylchloramide as a topical antiseptic, antidandruff agent, etc. and that one skilled in the art would reasonably have expected that such compositions would be useful in treating the particular skin diseases.

Applicants respectfully traverse. Wakeman neither discloses nor suggests the use of tosylchloramide compounds in the treatment of the particular skin diseases or even diseases that are remotely similar. The causes of the recited skin diseases are many and varied. Is the Examiner suggesting that Wakeman would render claims drawn to the treatment of ANY skin disease using a tosylchloramide composition obvious? This is an outrageous claim. It is well known that different ailments, even when caused by apparently similar microorganisms, require widely disparate treatments. The Examiner's claim is so far reaching as to border on being ridiculous. The Examiner's claim is equivalent to stating that, since penicillin is effective in the

treatment of certain bacterial infections, that it would then be obvious to use it to treat, e.g., the HIV virus that causes AIDS, since in the Examiner's opinion both the virus and the bacteria are "microorganisms". As the Applicants hope the Examiner will appreciate that this type of argument is completely inappropriate and ill-informed. The fact is that different ailments require different treatments, and unless such ailments are extremely close in both cause and manifestation (which is not the case here), the use of a compound in the treatment of one would not render obvious its use in the treatment of the other.

Similar arguments apply to the other references as well. DE1971256 is directed to a composition containing an agent which generates Singulett-oxygene and photons, respectively, and a process for the treatment of blood and blood products with said composition. Vandeveld is directed to an agent which acts against retrovirus group viruses, whereby the agent consists of a chlorinated organic compound which stably and lastingly releases chlorine when in solution. Harwardt is directed to the use of an oxygen generating compound as an antiseptic and for disinfection (see page 2, lines 3 and 4). As with Wakeman, none of these references discloses nor suggests a method for the treatment of the specifically claimed diseases or even diseases or conditions that could be considered closely related. In this respect, the differences between the treatment of the retroviruses of Vandeveld and the diseases of the present application are specifically recited on page 2, lines 6-19 of the present application.

In view of the above, Applicants respectfully request withdrawal of this rejection.

### **CONCLUSION**

In view of the foregoing comments, Applicants submit that claims 1-20 are in condition for allowance. Applicants respectfully request early notification of such allowance. Should any issues remain unresolved, the Examiner is encouraged to contact the undersigned to attempt to resolve any such issues.

If any fee is due in conjunction with the filing of this response, Applicants authorize deduction of that fee from Deposit Account 06-0308.

Respectfully submitted,

**FAY, SHARPE, FAGAN,  
MINNICH & MCKEE, LLP**

Date: \_\_\_\_\_

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*Joseph E. Waters*

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Joseph E. Waters  
Reg. No. 50,427  
Scott A. McCollister  
Reg. No. 33,961  
1100 Superior Avenue  
Seventh Floor  
Cleveland, OH 44114-2518  
216/861-5582